DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

December 22, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-25

George H. Kuetgens, President
Salmolux, Inc.
34100 9th Avenue South
Federal Way, Washington 98003

WARNING LETTER

Dear Mr. Kuetgens:

We inspected your firm located at 34100 9th Avenue South, Federal Way, Washington, on June 8, 1999, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP Regulations). These deficiencies, some of which were previously brought to your attention, cause your cold smoked salmon products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in the Food and Drug Administration's (FDA) homepage at www.fda.gov.

1. You must have a HACCP plan that lists the critical control points, in order to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for cold smoked salmon does not list the critical control point of cooler storage for controlling the food safety hazard of *Clostridium. botulinum* toxin formation.

2. You must verify that your HACCP plan is adequate to control the food safety hazards that are reasonably likely to occur, in order to comply with 123.8(a). However, your firm did not verify that the critical limit of the 15 pound nitrite added at the brine step for cold smoked salmon results in a level of 100-200 ppm nitrite. Based on our analysis of ten subsamples of vacuum packaged cold smoked salmon, sodium nitrite levels ranged from 28.4 ppm to 56.5 ppm.

   You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). Although your firm's HACCP plan for cold smoked skin-on halibut does list a critical limit of 60° Fahrenheit for brine temperature at the brining critical control point, it is not adequate to control growth of pathogens.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. Pertinent sections of the Act and the regulations are enclosed for your review.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive S.E., Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,

Kristy D. Thies

Kristy D. Thies
Acting District Director

Enclosures:
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement